

REMARKS

Claims 1-25 are pending in the application. Claims 15-20 and 22 have been amended. Claim 24 includes subject matter from claims 1, 2, and 3. Claim 25 includes subject matter from claims 1, 3, and 11. No new matter has been added. Entry of the amendment is respectfully requested. Reconsideration is respectfully requested.

Amendments to the Specification

The amendments to the specification are made to correct typographical errors in the document as originally filed. The incorrectly spelled “load” has been replaced with “loan.” Also, the incorrectly spelled “waist” has been replaced with the “waste.” The Abstract has been shortened to less than 150 words. No new matter has been added to Applicants’ disclosure by way of the amendments.

Claim Rejections

Claims 15-22 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15-22 have been rejected as being incomplete for omitting essential elements, i.e. a second type of medical item. Claims 18 and 19 have been rejected as being indefinite for reciting “DEA Form 222.” It is believed that the Examiner intended to apply this rejection to claims 18 and 20. As such, the comments addressing this rejection below are directed to claims 18 and 20.

Claims 1-23 have been rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,003,006 to Colella, et al.

35 U.S.C. § 112 Rejections: Claims 15-22

Claims 15-20 and 22 have been amended to recite “a second type of medical item” rather than a “third type of medical item.” The amendments to claims has been made to correct an inadvertent grammatical error and not by way of limiting the subject matter of the claims. It is respectfully requested that the rejection of claims 15-22 as being indefinite be withdrawn.

Claims 18 and 20 have been amended to remove reference to “DEA Form 222.” In accordance with the originally filed specification (e.g., page 176, line 16-page 177 line 7; page 186, lines 20-22; page 187, lines 2-4; page 195, lines 20-21; and page 196, lines 1-19), the claims have been amended to recite “a government-approved drug monitoring form.” The amendments to claims 18 and 20 are made to clarify Applicant’s invention and not by way of limiting their scope.

35 U.S.C. § 103 Rejections: The Applicable Legal Standards

The Office has the responsibility to present a *prima facie* case of obviousness under 35 U.S.C. § 103. An Applicant is entitled to a patent if the Office fails to establish a *prima facie* case of obviousness. *In re Oetiker*, 24 U.S.P.Q. 2d 1443 (Fed. Cir. 1992). In determining obviousness under 35 U.S.C. § 103, the invention must be considered “as a whole.”

Any modification of the cited reference in order to arrive at Applicants’ invention must be motivated by the cited art. *In re Deminski*, 230 U.S.P.Q. 313 (Fed. Cir. 1986). Applicants’

own disclosure may not serve as a template to piece together the teachings of the prior art to render the claimed invention obvious. *In re Fritch*, 23 U.S.P.Q. 2d 1780 (Fed. Cir. 1992). There must be a reason or suggestion in the prior art for selecting the claimed procedure, other than knowledge learned from Applicants' disclosure. *In re Dow Chemical*, 5 U.S.P.Q. 2d 1529 (Fed. Cir. 1988). Further, the motivation for modifying a reference cannot be found if the reference actually "teaches away" from the claimed invention. *In re Gurley*, 31 U.S.P.Q. 2d 1130 (Fed. Cir. 1994).

It is respectfully submitted that the 35 U.S.C. § 103 rejections set forth in the Action do not meet these burdens.

The Pending Claims Are Not Obvious Over Colella, et al.

Claim 1

The Applicants respectfully submit that US Patent No. 6,003,006 to Colella, et al. ("Colella") does not teach or suggest Applicants' claimed method.

Colella does not teach or suggest step (a)

Step (a) recites "storing a plurality of types of medical items in a plurality of storage locations within a pharmacy." Colella does not teach or suggest a plurality of storage locations within a pharmacy. Contrarily, Colella actually teaches away from having a centralized "on-site" storage location. For example, Colella teaches (at Col. 4, lines 30-40) that "the present invention is especially designed to enable health care providers to reduce their own inventory of drugs and shift inventory management responsibilities to the drug distribution center." Colella further teaches (at Col. 5, lines 44-53) that "the distribution center ships the requested unit dose packages of drugs in 'totes' (shipping containers) 60 which are predesignated for a particular

DDM [drug dispensing machine] at the health care facility. Therefore, instead of the health care facility having to spend resources on getting the right drugs to the right DDM, the DCC [drug distribution center] can accomplish this in a much faster manner through its tracking of data received from the CPC [central pharmacy computer] . . . and the subsequent shipping of predesignated and properly labeled totes.”

Colella teaches using a centralized computer to monitor drug levels at particular drug dispensing machines and to order low unit doses of drugs from an off-site distribution center. The drugs can then be packaged at the distribution center for delivery to a particular drug dispensing machine. Colella teaches (at Col. 2, lines 27-31) that “Once the drugs are packaged, they may be warehoused at a drug distribution center. When a health care provider requires drugs the drug distribution center delivers the low unit measure packages in accordance with the hospital’s current needs.” Colella further teaches (e.g., Col. 4, lines 17-26) that the remaining inventory of drugs ordered, but not sent, is maintained at the distribution center. Also, in Colella the health care facility only receives medical items that it will shortly use (e.g., Col. 4, lines 34-36). That is, the medical items that are not needed in a DDM are stored at the distribution center warehouse, not at the pharmacy. Thus, Colella does not teach or suggest “storing a plurality of types of medical items in a plurality of storage locations within a pharmacy” as Applicants claim.

Modification of Colella in the manner alleged would destroy the explicit teachings of the reference as noted above. However, an obviousness rejection cannot be based on a combination of features if making the combination would result (which is the current situation) in destroying the utility of the device shown in the prior art reference. Note *In re Fine*, 5 USPQ2d 1598-99

(Fed. Cir. 1988).

Colella does not teach or suggest step (b)

According to step (b), data corresponding to each type of medical item and its corresponding storage location in the pharmacy is stored in a data store. Colella does not teach or suggest a data store including data corresponding to each type of medical item and its corresponding storage location in a pharmacy. Where does Colella even teach or suggest storing data on storage locations within a pharmacy? Where does Colella even teach or suggest pharmacy storage locations? Where does Colella even teach or suggest the linking of medical items to their corresponding storage locations? Even if it were somehow possible to store drugs at a pharmacy in Colella, what prevents the drugs from being stored at the same single location as opposed to different locations? For example, what prevents the drugs from being stored in the same location (e.g., a room), either randomly stored or stored on racks having written labels? There is no evidence that Colella has a pharmacy with different storage locations, nor the storing of data regarding the storage locations in a data store. Even if it were somehow possible to store the location of drugs in a pharmacy in Colella, there is no evidence that the drugs would not be given or have the same location (i.e., the same pharmacy address).

Furthermore, Colella teaches using a single location for tracking different drugs. For example, Colella teaches (Col. 3, lines 60-67) that each DDM, which may have a plurality of drawers for storing drugs, may be uniquely identified by its single physical location within the health care facility. That is, the drugs in a DDM are not tracked by where they reside in the DDM. Rather, the location of drugs is assigned to the location of the DDM in which the drugs reside (Col. 1, lines 55-57; Col. 2, lines 38-43; Col. 4, lines 43-44; Col. 5, lines 17-18). Colella

does not teach or suggest storing data corresponding to different drug storage locations within a DDM. All drugs in a DDM have the same location for purposes of tracking. It follows that Colella teaches away from storing data corresponding to storage locations within a pharmacy. The Office has not established a *prima facie* showing of obviousness.

Colella does not teach or suggest steps (c) and (d)

Claim 1 includes the step of providing input indicative of “taking” a first quantity of a first type of medical item “from” its storage location in a pharmacy for use in a second location or in an activity. Data responsive to the input is generated and stored. Where does Colella teach or suggest generation and storage of data associated with the taking of a medical item type from a particular storage location in a pharmacy? The Office has not established a *prima facie* showing of obviousness.

Colella does not teach or suggest steps (e), (f), and (g)

Claim 1 includes the step of generating input indicative of “use” of a second quantity of the first type of medical item at the second location or in an activity. Data responsive to this input is generated and stored. The claimed invention includes a step (step g) of comparing the “taking” data (step d) and the “use” data (step f).

As the Examiner correctly admits, “Colella et al do not teach the steps of comparing the inputs and outputting a difference.” (Office Action, p. 3, para. 7). In fact, since Colella teaches away from storage locations in a pharmacy as previously discussed, Colella cannot be said to teach or suggest first generating a “taking” input to be later compared with a “use” input. There is no teaching or suggestion in Colella that one of ordinary skill in the art would be motivated to modify the reference to provide the claimed invention.

Additionally, to the extent that the Examiner relies (at Action page 3, lines 15-16) on personal knowledge of “the tracking industry” to support modification of the cited reference, Applicants hereby request an affidavit according to the provisions of 37 C.F.R. § 1.104(d)(2).

Applicants also respectfully traverse the Examiner’s assertion on the basis that it is not supported by any reference to prior art. The Patent Office is not permitted to rely merely on assertions of knowledge as the basis for rejecting claims. Furthermore, an assertion not based on any evidence in the record lacks substantial evidence support. *In re Zurko*, 258 F.3d 1379, 59 USPQ2d 1693 (Fed. Cir. 2001). *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). Applicants respectfully submit that the record lacks the requisite supporting evidence. It follows that the Action does not factually support any *prima facie* conclusion of obviousness.

The data associated with the “taking” of a first quantity of a first type of medical item from the pharmacy is compared to data associated with the “use” of a second quantity of the first type of medical item at a particular second location or in a particular activity. The claimed step (g) of comparing at least a portion of the generated data links the “taking” event at the first location and the “use” event at the second location or in an activity. Colella does not teach or suggest the association of such data.

As previously discussed, Colella clearly teaches the need to reduce or eliminate the stores of medical items “on site” in the pharmacy. (Col. 4, lines 32-34). Colella provides that information, such as stocking needs, from the drug dispensing machine is directed to an off-site facility where medical items are packaged and labeled for distribution directly to the particular drug dispensing machine (Col. 5, lines 44-56). Thus, Colella actually teaches away from any need of medical item storage within a pharmacy. It follows that Colella does not teach or

suggest a link between “taking” data (related to the taking of a medical item from a first storage location in a pharmacy) and “use” data (related to the use of a medical item at a second location or in an activity).

The Examiner may not (as in the current situation) use the Applicants’ disclosure as a template to modify Colella. The attempts to modify Colella are clearly attempts at hindsight reconstruction of Applicants’ claimed invention, which is legally impermissible and does not constitute a valid basis for a finding of obviousness. *In re Fritch*, 22 USPQ2d 1780 (Fed. Cir. 1992). The rejections, which lack the necessary evidence and rationale, are based on knowledge gleaned only from Applicants’ disclosure.

Thus, a *prima facie* case of obviousness has not been established. Furthermore, it would not have been obvious to one having ordinary skill in the art to have modified Colella as alleged. The applied prior art is devoid of any such teaching, suggestion, or motivation for modifying Colella as alleged so as to have produced the recited invention.

Additional Comments

Applicants have not necessarily presented all of the reasons as to why the Colella does not render the claim obvious. Nevertheless, Applicants’ remarks herein have shown that when the invention is taken as a whole, Colella does not teach or suggest the claimed method. Additionally, one of ordinary skill in the pertinent art would not have been motivated by the teaching of Colella to have made the modifications proposed by the Examiner. The Office has therefore failed to provide a *prima facie* case of obviousness within the meaning of 35 U.S.C. § 103(a). Thus, it is respectfully submitted that the rejections should be withdrawn.

The Dependent Claims

Each of the dependent claims depends directly or indirectly from independent claim 1. Independent claim 1 has been previously shown to be allowable. Thus, it is asserted that the dependent claims are allowable on the same basis.

Furthermore, each of the dependent claims additionally recites specific features and relationships that patentably distinguish the claimed invention over the applied art. The applied art does not teach or suggest the features and relationships that are specifically recited in the dependent claims. Thus, it is respectfully submitted that the dependent claims are further allowable due to the recitation of such additional features and relationships. Colella does not disclose or suggest the features and relationships that are specifically recited in the claims.

For example, claim 2 recites a further step of providing at least one output indicative of at least one difference between the data included in the data stores. As noted above, the Office admits that “Colella et al do not teach the steps of comparing the inputs and outputting a difference.” It follows that the Office expressly states that Colella fails to teach the method recited in claim 2. Further, the reference does not provide motivation for a modification of the reference in such a way as to provide Applicants’ invention. Because the reference does not teach or suggest a comparison of data, it necessarily does not teach providing an output indicative of a difference in the data.

Claims 3 and 4 each depends from claim 2 and further define the claimed output. Therefore, the comments directed to claim 2 apply equally well to claims 3 and 4 and are incorporated herein by reference.

Claim 5 provides that the “taking” event recited in claim 1 is associated with a “stocking”

event at a remote storage location. Claim 5 further provides for an input indicative that the stocking event has occurred at the remote location. The Colella reference does not teach or suggest generation of data associated with a “taking” event. Therefore, it necessarily cannot teach associating the “taking” event with a stocking function at the remote storage location and providing input that the stocking function has occurred.

Claim 6 depends from claim 5. As such, the comments directed to claim 5 apply equally well to claim 6 and are incorporated herein by reference.

The method of claim 7 provides a “return” event of a fourth quantity of the first type of medical item from the remote storage location to the pharmacy and the provision of input and generation of data indicative of the return event. The reference does not teach or suggest a return event as Applicants claim.

Claims 8 and 9 each depend from claims 7. Therefore the comments directed to claim 7 apply equally well to claims 8 and 9 and are incorporated herein by reference. Additionally, as noted above, the Examiner states that the reference does not teach a comparison of inputs and outputting a difference. Since the reference does not teach or suggest a “return” event, it necessarily cannot teach or suggest generation and comparison of data related to the “return” event.

Claim 10 references a “compounding” activity. Nowhere in the cited reference is there any teaching or suggestion concerning “taking” a first quantity of the first type of medical item for “use” in a compounding activity.

Claim 11 references a “wasting activity.” Nowhere in the cited reference is there any teaching or suggestion concerning “use” of a medical item being in a “wasting activity.”

Claim 12 includes the steps of creating a compound using the first type of medical item, providing input indicative of storing the created compound in a storage location in the pharmacy, and storing data responsive to the input. The reference does not teach or suggest creating a compound from a first type of medical item stored in the pharmacy. The reference does not teach storing the created compound in the pharmacy and generating associated data. The reference clearly teaches obtaining drugs from a distribution center to be directly stocked at a DDM (Col. 5, lines 33-56). There is no teaching or suggestion to modify the reference to obtain Applicants' invention. Again, the Examiner may not use Applicants' disclosure as a template for modification of the reference absent some suggestion or teaching to do so within the reference itself.

Claims 13 and 14 depend from claim 12. As such, the comments directed to claim 12 apply equally well to claims 13 and 14 and are incorporated herein by reference. In addition, as noted above, the Examiner states that the reference does not teach comparison of inputs. Because the reference does not teach the steps of creating a compound and storing it in a pharmacy, it necessarily cannot teach comparison of data associated with such steps. Further, the reference does not teach or suggest the step of providing an input responsive to a comparison indicating a discrepancy and the step of including data representative of the discrepancy in at least one data store.

Claims 15-22 each ultimately depend from claim 1. As such, the comments directed to claim 1 above apply equally well to claims 15-22 and are incorporated herein by reference. Further, claims 15-22 are directed toward "external activities" between health care facilities such as borrowing and returning, and loaning and receiving back medical items. The external

activities are accompanied by providing input indicative of the activity and including data in a data store representative of the activity. The reference does not teach or suggest movement of medical items between health care facilities and the generation and storage of data indicative of such movement. Thus, claims 15-22 cannot be obvious in view of the cited reference. Absent some teaching or suggestion to do so, it is improper for the Examiner to modify the reference to arrive at Applicants' claimed invention.

Further, claims 18, 20, and 21, as amended, refer to the generation of a "government-approved drug monitoring form" corresponding to the external activity. The reference does not teach or fairly suggest provision of an electronic representation of such a form to track movement of medical items between health care facilities. As to claim 21, since the reference does not teach or suggest generation of an electronic version of the claimed form, it necessarily cannot teach or suggest automatic population of at least one field in the form.

As the Examiner states: "Colella et al do not teach that the items are used in a compounding activity or are wasted, nor does Colella teach that items are borrowed or loaned." (p. 3, para. 7). To the extent that the Examiner relies on personal knowledge of the art to support modification of the cited reference, Applicants hereby request an affidavit according to the provisions of 37 C.F.R. § 1.104(d)(2).

Claim 23 recites computer readable media operative to cause at least one processor to carry out the method steps recited in claim 1. The reference does not teach the method as claimed. The reference is directed to a system having a central pharmacy computer that receives dispensing information from the drug dispensing machine and orders replacement inventory from an off-site drug distribution center. The replacement inventory is packaged, off-site, and

labeled for delivery to the particular drug dispensing machine. As the method of claim 1 has been shown to be patentable over the cited art, the operative media to carry out the method steps is thus similarly patentable.

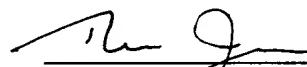
Each of the dependent claims has been shown to be non-obvious when taken as a whole in view of the cited art. Thus, the Examiner has failed to establish a *prima facie* case of obviousness and withdrawal of the rejections is respectfully requested.

Conclusion

Each of Applicants' pending claims specifically recite features, relationships, and steps that are neither disclosed nor suggested in any of the applied prior art. Furthermore, the applied prior art is devoid of any such teaching, suggestion, or motivation for modifying features of the applied art so as to produce Applicants' invention. Allowance of all of Applicants' pending claims is therefore respectfully requested.

The undersigned will be happy to discuss any aspect of the Application by telephone at the Office's convenience.

Respectfully submitted,



Ralph E. Jocke Reg. No. 31,029
WALKER & JOCKE
231 South Broadway
Medina, Ohio 44256
(330) 721-0000